REMARKS

Applicant requests reconsideration of the application in view of the foregoing amendments and the discussion that follows. The status of the claims as of this response is as follows: Claims 1-32 are pending. Claims 7-12, 26, 28, 29 and 32 have been canceled herein. Claims 1, 6, 13, 19, 20, 21, 24, 27, 30 and 31 have been amended herein.

The Amendments

Claim 1 was amended to delete the embodiments where R^1 and R^2 are taken together to form a ring. Support therefor is in the specification, for example, original Claim 1.

Claims 13, 20 and 21 were amended in a manner similar to that for Claim 1.

Claims 6, 19 and 24 were amended to refer to enzyme labels, luminescent labels and radioisotope labels. Support therefor is in the specification, for example, the original claims and page 1, lines 18-19, and page 8, lines 15-25.

Claims 27, 30 and 31 were amended to refer to protein immunogenic carriers and non-poly(amino acid) immunogenic carriers. Support therefor is in the specification, for example, the original claims and page 9, lines 10-24.

Rejection under 35 U.S.C. 112

Claims 1-32 were rejected under the second paragraph of the above code section as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action alleges that Claims 1, 7, 13, 20, 27 and 28 recite the term "immunogenic carrier", "label" and/or "acid salts" and it is not clear what "immunogenic carrier" or "label" is encompassed by the terms as immunogenic carrier may include proteins, adjuvant and other non-protein substances and label may include various labeling agent such as fluorescein, cyanine, enzymes, radioactive substance, electrophoretic tag, etc. Therefore, concludes the Office Action, it is unclear what is intended by the terms immunogenic carrier or label.

Applicant respectfully traverses this ground of rejection. The terms "immunogenic carrier" and "label" are discussed in detail in the specification, for example, page 9, lines 10-24 and page 8, line 15, to page 9, line 9. In addition, these terms are well-known to those skilled in the assay art.

Claims 1 and 7 were also rejected as indefinite because, asserts the Office Action, it is not clear what is encompassed by the term "acid salts". Applicant respectfully traverses this ground of rejection. The term "acid salts" is defined in the specification, for example, page 8, lines 9-11. Furthermore, the term is well-known to the skilled artisans in the chemistry area.

Claims 1 and 7 were rejected for recitation of the term "protecting group". The Office Action contends that it is not clear what is encompassed by this term because "protecting group" is a general term which includes numerous groups for protection of functional groups -OH, -NH, -SH, -COOH and -CO. Therefore, concludes the Office Action, these claims are vague and indefinite for not clearly defining the protecting group. First of all, the term is used in the claims for a substituent on either an -O- or -N- functionality. Second, the specification discusses in detail what is meant by the term. See, for example, page 14, lines 15-26. Finally, the term is well-known to those skilled in the art.

With respect to claims 21, 25, 26, 29 and 30, the Office Action alleges that it is not clear whether "antibody" used in the method is raised against a compound of what formula, i.e., against what hapten immunogen conjugate? Claims 26 and 29 have been canceled, thus, rendering moot the rejection of those claims. In each of Claims 21, 25 and 30, a label conjugate in accordance with embodiments of the present invention is recited. Consequently, the claimed methods are intended to include any antibody specific for the designated compound since the patentability of the methods is determined by the label conjugate and not the antibody. In addition, antibodies are discussed in detail in the specification, for example, page 17, line 9, to page 18, line 29.

The Office Action contends that it is not clear what is encompassed by the term "analog" in Claims 27, 28 and 31. The term "analog" is defined in the specification, for example, page 18, line 30, to page 19, line 29.

With respect to claims 12 and 19, the Office Action asserts that it is not clear what is encompassed by the terms "enzyme", "luminescer" and "radioisotopes" as these are generic terms and my include a variety of enzymes, luminescers and radioisotopes. Applicant has amended the above claims to refer to enzyme labels, luminescent labels and radioisotope labels. As mentioned above, a discussion of labels is found in the specification, for example, page 8, line 15, to page 9, line 9. The use of the above as labels in assays is well known in the art and the terms are understood by one skilled in the art.

The Office Action alleges that the term "immunogenic protein" in claims 27, 28 and 32 is confusing. Applicant submits that the amendments to the above claims in this regard obviates this ground of rejection.

Rejection under 35 U.S.C. 102

Claims 1-24, 26, 28, 29 and 32 were rejected under 35 U.S.C. 102(a) as being anticipated by Hui, *et al.* (EP 1,340,981 A2) (Hui). The reference discloses compounds including haptens, intermediates, and immunogens that are useful in the production of antibodies specific for the methylenedioxy class of amphetamine derivatives.

Claims 7-12, 26, 28, 29 and 32 were canceled, thus rendering the above rejection moot with respect to those claims. Without acquiescing in the rejection of the aforementioned claims, Applicant submits that amended Claims 1, 13, 20 and 21 and claims depending therefrom are patentable over Hui. The reference does not disclose or suggest the compounds of the present claims.

The Office Action makes the following statement: "It is noted that the claimed compounds wherein R_1, R2=cycle and R3, R4, R7, R8 =H or alkyl is anticipated by MDA, MDMA or MDEA (see Hui et al, paragraph [0002])." Applicant wishes to point out that the claims as originally written included the language that "when R^1 is taken together with R^2 to form a ring, at least one of R^3 or R^4 is $-(CH_2)_nC(O)R^5$ or $-(CH_2)_nR^5$. Accordingly, the original claims did not include MDA, MDMA or MDEA.

Claims 1-24, 26, 28, 29 and 32 were rejected under 35 U.S.C. 102(b) as being anticipated by Rouhani, *et al.* (GB 2361473 A) (Rouhani). Rouhani discusses

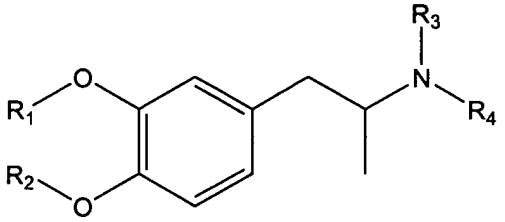
ecstasy-class analogs and the use of the same in detection of ecstasy-class compounds. The reference discloses certain immunogens for generating antibodies and also discloses certain enzyme conjugates.

Claims 7-12, 26, 28, 29 and 32 were canceled, thus rendering the above rejection moot with respect to those claims. Without acquiescing in the rejection of the aforementioned claims, Applicant submits that amended Claims 1, 13, 20 and 21 and claims depending therefrom are patentable over Rouhani. The reference does not disclose or suggest the compounds of the present claims.

Double Patenting

Claims 1-32 were provisionally rejected under the "judicially created doctrine of double patenting" over claims 1-37 of copending Application No. 10/736,005 (the '005 application). The Office Action alleges that Claims 1-37 of the referenced patent are drawn to a compounds of formula I and II (claims 1 and 7) which anticipate formula I and II (claims 1 and 7) of the present application. Furthermore, continues the Office Action, the referenced patent is also drawn to methods and kits comprising the same steps, ingredients and essentially the same composition as claimed in the cited claims of instant application.

The '005 application is directed in some embodiments to compounds of the formula:



Formula I

wherein: R^1 is H, lower alkyl, a protecting group, or is taken together with R^2 to form a ring,

R^2 is H, lower alkyl, $-(CH_2)_nSCH_2C(O)R^6$ or $-(CH_2)_nC(SO_2R^6)=CH_2$, or is taken together with R^1 to form a ring,

R^3 and R^4 are independently H or lower alkyl or a protecting group, or,

when R^1 is taken together with R^2 to form a ring, at least one of R^3 or R^4 is $-C(O)(CH_2)_nR^5$, $-C(O)(CH_2)_nNHC(O)R^5$, $-C(O)(CH_2)_nNHC(O)(CH_2)_nSR^5$, $-(CH_2)_nC(SO_2R^5)=CH_2$, $-(CH_2)_nSCH_2C(O)R^5$, or $-(CH_2)_nC(SO_2R^5)=CH_2$, or when R^1 is not taken together with R^2 to form a ring, at least one of R^1 and R^2 is not H or lower alkyl or a protecting group,

R^5 is H, -OH, -SH, -O-lower alkyl, halogen, NH_2, -succinimidyl, -maleimidyl, immunogenic carrier, or label,

R^6 is H, -OH, -SH, -O-lower alkyl, halogen, NH_2, -succinimidyl, -maleimidyl, immunogenic carrier, or label, and

n is an integer from 1 to 5,

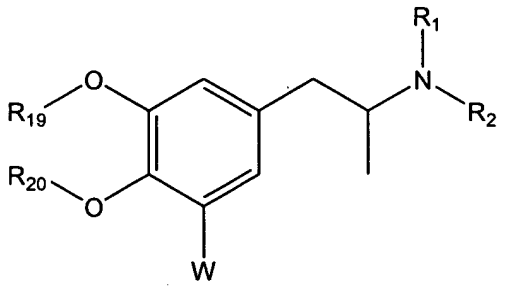
and including acid salts thereof.

The claims of the present application do not anticipate or suggest the compounds of the '005 application or vice versa. The claims of the two applications are not claiming the same subject matter. The claims of one application could be literally infringed without infringing the claims of the other application (assuming the applications issue as patents). Furthermore, the linking groups comprise different functionalities, not suggested by one another.

Claims 1-24, 26, 28, 29 and 32 were provisionally rejected under the "judicially created doctrine of double patenting" over claims 1-20, 26-27, 29-30, 32-39, 49-53, 59-63, 66-67 and 69 of copending Application No. 10/736,018 (the '018 application). The Office Action asserts that the subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject.

Claim 1 of the '018 application recites as follows:

A compound of the formula:



Formula I

wherein: R^{19} is lower alkyl or is taken together with R^{20} to form a ring, which may be a five- or six-member ring, usually a five-member ring;

R^{20} is lower alkyl, or is taken together with R^{19} to form a ring as discussed above,

R^1 is H or lower alkyl,

R^2 is H, lower alkyl, a protecting group or

(a) $-(CH_2)_aC(O)(CH_2)_bSR^3$, wherein a is 0 to 5, b is 1 to 5 and R^3 is H or lower alkyl or $(CH_2)_cC(O)NR^4R^5$ wherein R^4 is H or lower alkyl and R^5 is H, an immunogenic carrier or a label, or

(b) $(A)_d(Q)_n$ wherein Q is H or $-(CH_2)_eCH(R^8)(CH_2)_fOC(O)(CH_2)_gR^9$ being H only when d is 1 wherein A is $-C(O)(CH_2)_hC(O)NR^{10}((CH_2)_jO(CH_2)_kO)_m(CH)_2NR^{11}-$, d is 0 or 1, n is 0 or 1 wherein one of d or n is 1, h is 1 to 5, R^{10} is H or lower alkyl, j is 1 to 5, k is 1 to 5, m is 1 to 3, R^{11} is H or lower alkyl, e is 1 to 5, R^8 is OH or H, f is 1 to 5, g is 0 to 5, and R^9 is H, an immunogenic carrier or a label;

W is H or JR^{14} being H when R^2 is other than H or lower alkyl, wherein

J is O or S,

R^{14} is H, lower alkyl, a protecting group, or $-(CH_2)_rC(O)NR^{15}(CH_2)_s(D)_tR^{16}$, wherein r is 1 to 5, R^{15} is H or lower alkyl, s is 1 to 5, D is S, O or N, t is 0 or 1 being 0 when R^{16} is maleimidyl or succinimidyl, R^{16} is H, maleimidyl, succinimidyl, or $-(CH_2)_qC(O)NR^{17}R^{18}$,

q is 1 to 5,

R^{17} is H or lower alkyl,

R^{18} is H, lower alkyl, an immunogenic carrier or label,

and including the acid salts thereof.

The claims of the present application do not anticipate or suggest the compounds of the '005 application or vice versa. The linking groups comprise different functionalities, not suggested by one another. The claims of the two applications are, therefore, patentably distinct.

The Office Action further argued that there is no apparent reason why applicant

would be prevented from presenting claims corresponding to those of the instant application in the other copending application and referred to *In re Schneller,* 397 F.2d 350, 158 USPQ 210 (CCPA 1968) and MPEP § 804. Applicant assumes that this rejection based on *In re Schneller* has been approved by the Technology Center Director as required by MPEP § 804.

The double patenting rejections mentioned above are not maintainable. In any event the conflicting claims have not been patented and, thus, any consideration of the need for a terminal disclaimer is premature.

Conclusion

Applicant has demonstrated that Claims 1-6, 13-25, 27, 30 and 31 satisfy the requirements of 35 U.S.C. 112 and 102. Furthermore, the present claims are patentably distinct over the claims of the above-mentioned co-pending applications. Allowance of the above-identified patent application, it is submitted, is in order.

Respectfully submitted,

Theodore J. Leitereg
Attorney for Applicant
Reg. No. 28,319

Theodore J. Leitereg
31420 Pennant Ct.
Temecula CA 92591
(602) 369-1751